

Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 146-148, 150-177, 179-203, 233, and 237-244 are pending in the application, with claims 146-148, 176, 177, and 233 being the independent claims. Claims 149, 178, 204-232, and 234-236 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 146-148, 176, 177, and 233 have been amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

II. The Amendments

Claims 146-148, 176, and 177 have been amended by deleting the reference to specific allergic diseases other than atopic dermatitis. Claim 233 has been amended by replacing "selected from the group consisting of: food allergy, atopic dermatitis and allergic rhinitis" with "atopic dermatitis." Support for these amendments can be found at page 5, lines 23-27, and at page 6, lines 5-7 and lines 27-29, of the specification as filed.

Claim 146 has also been amended by deleting the phrases "inhibiting or" and "inhibit or." Support for these amendments can be found at page 4, lines 20-24, and in Examples 1-2, 1-3, 2-2, and 3 of the specification as filed.

Claim 176 has also been amended by replacing the phrases "inhibiting histamine release" and "inhibit histamine release" with "decreasing histamine release" and

"decrease histamine release," respectively. Support for these amendments can be found at page 4, lines 14-30, and in Example 5 of the specification as filed.

Accordingly, no new matter is believed to have been added by the amendments and their entry is respectfully requested.

III. The Rejections

A. Rejections Under 35 U.S.C. § 112, first paragraph

Claims 146, 149-176, 178-203, 204, and 207-232 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to enable a person skilled in the art to use the invention. Specifically, the Examiner states that "the specification does not reasonably provide enablement for inhibition of IgE production or inhibiting histamine release in a mammal in need thereof." (*See* Office Action at page 2). Applicants respectfully traverse this rejection.

1. Legal Principles of the Enablement Requirement

The test for enablement is whether one of ordinary skill in the art, given the disclosure at the time of filing, could make and use the claimed invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). In order to establish a *prima facie* case of lack of enablement, *the Examiner has the initial burden* to set forth a reasonable basis to question the enablement provided for the claimed invention. *See In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). To satisfy this burden, "it is incumbent upon the Patent Office . . . to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to *back up assertions of its own with acceptable evidence or reasoning which is inconsistent with*

the contested statement." See *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971) (emphasis added).

2. *The Examiner Has Not Met the Burden of Showing a Lack of Enablement*

The Examiner asserts in the Office Action that Applicants' specification "does not enable any person skilled in the art . . . to practice the invention commensurate in scope with these claims." Yet the Examiner has failed to provide any sound reasoning or objective technical evidence whatsoever to support this broad assertion. *Indeed, conspicuously absent from the rejection, which spans pages 2-5 of the Office Action, is a single cite to the scientific literature that would refute or even cast doubt upon the teachings or data in Applicants' specification.*

In fact, the claimed methods have been exemplified in numerous Experimental Examples such that a person of ordinary skill in the art at the time of filing would have been able to practice the invention commensurate in scope with the claims without undue experimentation. Applicants respectfully assert that no specific scientific evidence or reasoning has been presented to indicate otherwise and, therefore, the reasons for the rejection are insufficient to establish a *prima facie* case of non-enablement.

3. *Examiner's Construction of the Term "Inhibit" or "Inhibiting"*

The Examiner continues to assert that the terms "inhibit" and "inhibiting" is synonymous with the terms "prevention" and "curing" and that the terms "inhibit" and "inhibiting" circumscribe methods of treatment having absolute success. (Office Action at page 4). However, the Examiner's construction of the term is not consistent with the Applicants' usage of the term in the specification. Rather, the plain and ordinary construction of the term "inhibit" is consistent with the hindered IgE production

described in Experimental Example 1 and the hindered histamine release described in Experimental Example 5. The plain and ordinary construction of the term "inhibit," as provided in Applicants' Amendment and Reply of April 6, 2009, does not require absolute disease prevention or a cure.

Nevertheless, in an effort to expedite prosecution, and without acquiescing in the propriety of the rejection, Applicants have amended claims 146 and 176 to eliminate the term "inhibit" or "inhibiting." Accordingly, Applicants request that the rejection of pending claims 146, 150-176, and 179-203 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. Rejections Under 35 U.S.C. § 103

1. Obviousness Rejection #1

Claims 146-153, 155-183, 185-211, and 213-244 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Murad (U.S. Pat. No. 6,630,163) in view of Endres *et al.* (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo *et al.* (CN 1107308 A), Tsuboi *et al.* (JP 02202808 A), Wuthrich (*Clin. Exp. Allergy* 8(3):241-248), Lukacs *et al.* (U.S. Pat. Appl. No. 2002/0006410 A1), and Capetola *et al.* (U.S. Pat. No. 4,444,780). Applicants respectfully traverse the rejection.

a. Elements of a Prima Facie Case of Obviousness

In order to establish a *prima facie* case of obviousness, (1) the prior art reference (or references when combined) must teach or suggest all of the claim limitations; (2) there must be some reason, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine

reference teachings; and (3) there must be a reasonable expectation of success. M.P.E.P. § 2143. The Examiner has the burden of establishing a *prima facie* case of obviousness.

The invention as presently claimed is directed to methods of treating, alleviating or reducing one or more symptoms of atopic dermatitis via the oral administration of an extract of kiwifruit of the genus *Actinidia*.

b. Murad (U.S. Pat. No. 6,630,163)

At page 12 of the Office Action, the Examiner asserts that

Murad in fact teaches a method of treating dermatological conditions, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwifruit extract. See col. 8, lines 10-29. Inflammatory dermatoses encompasses the limitation atopic dermatitis.

Contrary to the Examiner's assertion, Murad does not teach methods for treating all dermatological disorders, or even methods aimed at treating all inflammatory dermatoses. Rather, Murad merely mentions the use of fruit extracts to treat a multitude of inflammatory dermatological conditions listed at col. 8, lines 2-12, and mentions kiwi in a laundry list of fruits. Murad contains only one working example in which a fruit extract is used for any therapeutic or preventive purpose: treating sun-exposed skin. Murad provides a laundry list of *non-allergic* inflammatory dermatoses that are contemplated for treatment, however, there is no working example showing that Murad kiwifruit extract compositions were ever used to treat such conditions, and Murad provides no specific teaching that would guide one of ordinary skill in the art on how the compositions would be used for such purposes. Murad does not disclose treatment of any *allergic disease*, much less *atopic dermatitis*, as recited in independent claims 146-148, 176, 177, and 233. Nor does Murad teach treating atopic dermatitis by *orally*

administering kiwifruit extracts. As such, the reference does not teach all of the claim limitations of any of the pending claims.

c. Endres et al. (DE 19758090 A1)

While Endres mentions using *Actinidia arguta* extracts to **topically** treat **non-allergic** inflammatory dermatological conditions, Endres does not disclose treatment of any **allergic** condition, much less **atopic dermatitis**, with extracts of kiwifruit of the genus *Actinidia*. Additionally, none of the examples in Endres teach **orally** administering a kiwifruit extract. Therefore, there is no suggestion or motivation to orally treat atopic dermatitis in a mammal in need thereof with kiwifruit extracts of the claimed invention simply by combining the Murad and Endres references. Additionally, the combined references fail to provide a reasonable expectation for successfully treating atopic dermatitis by orally administering a kiwifruit extract to a mammal in need thereof.

d. Udagawa (JP 61140510 A)

While Udagawa mentions the use of *Actinidia kolomikta* and *Actinidia polygama* fruit extracts in *cosmetics* and juices as a starting material in food, Udagawa does not teach addressing the mechanism underlying allergic disease or **orally** administering kiwifruit **extracts** to treat **atopic dermatitis** in a mammal in need thereof.

Again, there is no suggestion or motivation to treat atopic dermatitis with the claimed extracts of kiwifruit of the genus *Actinidia* simply by combining the Murad, Endres and Udagawa references. Additionally, the references combined fail to provide a reasonable expectation for successfully treating atopic dermatitis by orally administering a kiwifruit extract to a mammal in need thereof.

e. Luo et al. (CN 1107308 A)

Luo generally discusses the use of kiwi fruit extracts and beverages for the treatment of illness. Like Murad, Endres and Udagawa, Luo does not teach treating, alleviating or reducing one or more symptoms of *atopic dermatitis* by *orally* administering a kiwifruit *extract* to a mammal in need thereof. As such, the references combined fail to provide a reasonable expectation for successfully treating atopic dermatitis.

f. Tsuboi et al. (JP 02202808 A); Wuthrich (Clin. & Exp. Allergy 8:241-248); Lukacs et al. (U.S. Pat. Appl. Publ. No. 2002/0006410); and Capetola et al. (U.S. Pat. No. 4,444,780 A)

The Examiner has additionally cited Tsuboi, Wuthrich, Lukacs and Capetola. Tsuboi merely discusses oral and topical kiwifruit extract compositions. Wuthrich describes increased IgE production associated with atopic dermatitis. Lukacs discusses what is already known in the art by way of T_H1/T_H2 immune response mechanisms. Capetola describes a relationship between histamine release and edema and atopic dermatitis. Applicants submit that none of the cited references disclose *orally* treating, alleviating or reducing one or more symptoms of *atopic dermatitis* with extracts of kiwifruit of the genus *Actinidia* as recited in independent claims 146-148, 176, 177, and 233. Therefore, none of these references cure the deficiencies of Murad, Endres, Udagawa, and Luo.

g. Summary

The Examiner asserts that the combination of the Murad, Endres, Udagawa, Luo, Tsuboi, Wuthrich, Lukacs and Capetola references renders the invention obvious. As explained above, the claimed methods are non-obvious because the cited references (1)

do not teach (individually or in combination) the treatment of *atopic dermatitis* by *orally* administering kiwifruit *extracts* to a mammal in need thereof; (2) do not provide one of skill in the art with a reason to modify the references to arrive at the claimed invention; and (3) do not provide a reasonable expectation of success. As such, Applicants submit that with regard to the pending claims the Examiner has failed to make a *prima facie* case of obviousness.

Accordingly, it is respectfully requested that the rejection of pending claims 146-148, 150-153, 155-177, 179-183, 185-203, 233, and 237-244 under 35 U.S.C. § 103, as allegedly obvious, be reconsidered and withdrawn.

2. Obviousness Rejection #2

Claims 154, 184, and 212 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Murad (U.S. Pat. No. 6,630,163) in view of Endres *et al.* (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo *et al.* (CN 1107308 A), Tsuboi *et al.* (JP 02202808 A), Wuthrich (*Clin. Exp. Allergy* 8(3):241-248), Lukacs *et al.* (U.S. Pat. Appl. No. 2002/0006410 A1), and Capetola *et al.* (U.S. Pat. No. 4,444,780), and further in view of Suzuki *et al.* (U.S. 2002/0054923 A1). Applicants respectfully traverse the rejection.

Pending claim 154 depends from claim 151, which in turn depends from independent claims 146-148. Accordingly, claim 154 incorporates the limitations of claims 146-148 and 151. Pending claim 184 depends from claim 181, which in turn depends from independent claims 176 and 177. Accordingly, claim 184 incorporates the limitations of claims 176, 177, and 181. As discussed above, Applicants submit that neither Murad, Endres, Udagawa, nor Luo teach each and every claim limitation of the

pending claims. Additionally none of the references teach the mechanism underlying allergic disease, let alone orally administering kiwifruit extracts to treat *atopic dermatitis* in a mammal in need thereof. Applicants submit that Tsuboi, Wuthrich, Lukacs, Capetola, and Suzuki also do not disclose treating, alleviating or reducing one or more symptoms of *atopic dermatitis* with extracts of kiwifruit of the genus *Actinidia* as recited in independent claims 146-148, 176, and 177. Suzuki merely discusses kiwifruit extract compositions. As such, Applicants assert that there is no suggestion or motivation to combine these references with Murad, Endres and Udagawa. Moreover, a skilled person in the art would not have had a reasonable expectation of achieving the desired therapeutic results based solely on the cited references. As such, Applicants submit that with regard to the pending claims the Examiner has failed to make a *prima facie* case of obviousness.

Accordingly, it is respectfully requested that the rejection of pending claims 154 and 184 under 35 U.S.C. § 103, as allegedly obvious, be reconsidered and withdrawn.

3. Obviousness Rejection #3

Claims 146-153, 155-183, 185-211, and 213-244 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Forastiere *et al.* (*Thorax* 55:283-288 (2000)) in view of Endres *et al.* (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo *et al.* (CN 1107308 A), and further in view of Lee *et al.* (*Clin. Immunol.* 101(2):220-228 (2001) and Wei (U.S. Pat. No. 5,177,060 A). Applicants respectfully traverse the rejection.

Forastiere et al. (Thorax 55:283-288 (2000))

As stated in Applicants' Amendment and Reply of April 6, 2009, Applicants reiterate that Forastiere merely discusses treating asthma symptoms by administering common kiwifruit. This reference does not disclose administering any specific type of kiwifruit *extract*, let alone the kiwifruit extracts from *Actinidia arguta*, *Actinidia polygama* and *Actinidia kolomikta*. Nor does this reference teach alleviating the symptoms of *atopic dermatitis* by orally administering kiwifruit extracts. Thus, Forastiere fails to teach each and every limitation of the pending claims.

As discussed above, Applicants submit that neither Endres, Udagawa, nor Luo teach each and every claim limitation of the pending claims. Additionally, none of the references teach the mechanism underlying allergic disease or orally administering kiwifruit extracts to treat atopic dermatitis in a mammal in need thereof.

For the reasons provided above, Applicants assert that there is no suggestion or motivation to combine Forastiere, which teaches attenuation of asthmatic symptoms via vitamin C consumption, with Endres, Udagawa, or Luo. Moreover, a skilled person in the art would not have had a reasonable expectation of achieving the desired therapeutic results based solely on the cited references.

Applicants submit that Lee and Wei also do not disclose treating, alleviating or reducing one or more symptoms of *atopic dermatitis* with extracts of kiwifruit of the genus *Actinidia* as recited in independent claims 146-148, 176, 177, and 233. Lee merely discusses an association between asthma, histamine release, and serum IgE, IgG1, IgG2, T_H1 and T_H2 levels. Wei generally discusses an association between asthma and edema. As such, Applicants assert that there is no suggestion or motivation to combine these references with Forastiere, Endres, Udagawa, and Luo. Moreover, a

skilled person in the art would not have had a reasonable expectation of achieving the desired therapeutic results based solely on the cited references. As such, Applicants submit that with regard to the pending claims the Examiner has failed to make a *prima facie* case of obviousness.

Accordingly, it is respectfully requested that the rejection of pending claims 146-148, 150-153, 155-177, 179-183, 185-203, 233, and 237-244 under 35 U.S.C. § 103, as allegedly obvious, be reconsidered and withdrawn.

4. Obviousness Rejection #4

Claims 154, 184, and 212 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Forastiere *et al.* (*Thorax* 55:283-288 (2000)) in view of Endres *et al.* (DE 19758090 A1) and/or Udagawa (JP 61140510 A) and/or Luo *et al.* (CN 1107308 A), and further in view of Lee *et al.* (*Clin. Immunol.* 101(2):220-228 (2001), Wei (U.S. Pat. No. 5,177,060 A), and Suzuki *et al.* (U.S. 2002/0054923 A1). Applicants respectfully traverse the rejection.

The Examiner asserts that the combination of Forastiere, Endres and Udagawa renders obvious the pending claims. As explained above, the claimed methods are non-obvious because the cited references (individually and collectively) do not teach each and every claim limitation as they (1) do not teach methods of treating *atopic dermatitis* by *orally* administering kiwifruit *extracts* to mammals in need thereof; (2) do not provide a suggestion or motivation for reference combination; and (3) do not provide a reasonable expectation of success. As such, Applicants submit that the Examiner has failed to make a *prima facie* case of obviousness.

In view of the comments provided above, it is respectfully requested that the rejection of pending claims 154 and 184 under 35 U.S.C. § 103, as allegedly obvious, be reconsidered and withdrawn.

IV. Other Matters

A. The Objection to the Benefit Claim

At page 14 of the Office Action dated June 23, 2009, the Examiner asserts that upon considering the benefit claim to U.S. Provisional Appl. No. 60/405,295, "there is no support for certain allergic diseases (i.e. allergic conjunctivitis, contagious dermatitis, insect allergy), dilution ratios, concentration ranges, and solvents claimed herein." Accordingly, the Examiner has revoked the priority benefit date of August 23, 2002.

Applicants submit that the pending claims do not recite allergic conjunctivitis, contagious dermatitis, or insect allergy. Applicants also submit that all dilution ratios, concentration ranges and solvents recited in the pending claims find support in the provisional application as filed as follows:

CLAIM	SUPPORT in Prov. Appl. No. 60/405,295
151, 181, 238	See, for example, at page 5, lines 13-16.
152, 182	See, for example, at page 6, lines 34-36.
153, 183	See, for example, at page 6, lines 34-36.
154, 184	See, for example, at page 6, lines 34-36 and page 7, line 1.
155, 185	See, for example, at page 7, lines 3-4 and in Experimental Example 8.
156, 186	See, for example, at page 7, lines 3-4 and page 8, lines 34-36.
157, 187, 239	See, for example, at page 7, lines 6-7.
160, 189	See, for example, at page 7, lines 20-21.
161, 190	See, for example, at page 7, lines 20-21.
162, 191	See, for example, at page 7, lines 22-23.
166, 195	See, for example, at page 8, lines 1-5.

Accordingly, Applicants respectfully request that the objection to the priority of the benefit claim be reconsidered and withdrawn.

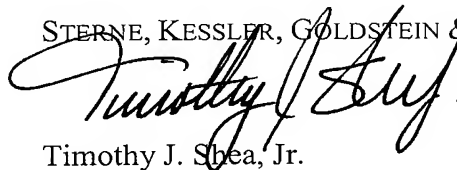
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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